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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,747	06/02/2000	Paul R. Burnett	Army 105	7935

30951 7590 09/05/2006

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,747	BURNETT ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2006 has been entered.

Claim Rejections 35 U.S.C. 251

2. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-23, 25-33 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Claims 15-23, 25-33 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

"wherein said subunit is gp 160".

Applicants assert that such amendemnts are supported by the specification at column 2, lines 40-45. However, the specification merely discloses recombinant gp 160 (rgp 160), and oligomeric gp 160 CDC451, and provide no support of gp 160 in general.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-23, 25-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "wherein said subunit is gp 160" lacks support from the application as originally filed for reasons as discussed above.

Claim Rejections-35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 15-23, 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice et al. (US 4,389,330, of record), in view of Schaffer et al. (WO 92/22654).

6. Tice et al teach at column 4, lines 65-67 that the microcapsules of the invention have utility in administering a variety of pharmaceuticals. At column 7, line 35 to column 7, line 49 it is taught how microcapsules of poly(lactide-co-glycolide) microcapsules are formed containing pharmaceutical active agents, wherein the process comprising solvent evaporation, and

extraction. At column 5, line 67 to column 6, line 16 Tice et al. teach the antigens, or vaccine that are capable of being formulated in the said microcapsules. At column 4, lines the size of the microcapsules are preferred to be between submicron to 250 μm in size. See, also the examples and the claims for more detailed description.

7. Tice et al. do not teach expressly the employment of gp 160 as the antigen or vaccine. However, Schaffer et al. teaches that gp 160 is a known antigen from a pathogen and is known to be used as vaccine for treatment of prophylactic treatment of viral infection.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make an encapsulated gp 160 vaccine according to method by Tice et al.

A person of ordinary skill in the art would have been motivated to make an microsphere containing gp 160 vaccine according to method by Tice et al. because gp 160 is a known antigen useful for therapeutical utility. As to the quoted functional properties, "conformationally native subunit. etc," it is noted that such property is deemed to describe a mechanism of action which would be inherent in the composition formed by the Tice et al reference See Examples 1 and 2, and claims 1 and 14 of Tice et al.

Claims 15-23, 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleland et al. (WO 95/11010).

8. Cleland et al. teach at the abstract, page 1, lines 16-32, page 8, line 8 to page 19, line 30 compositions of PLGA microspheres with antigen from HIV adhering thereto and the process of making the microspheres, which normally includes solvent evaporation and extraction.

9. Cleland et al. do not teach expressly the employment of gp 160 as the antigen or vaccine. However, Schaffer et al. teaches that gp 160 is a known antigen from a pathogen and is known to be used as vaccine for treatment of prophylactic treatment of viral infection.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make an encapsulated gp 160 vaccine according to method by Cleland et al.

A person of ordinary skill in the art would have been motivated to make an microspheres containing gp 160 vaccine according to method by Cleland et al. because gp 160 is a known antigen from HIV useful for therapeutical utility. As to the quoted functional properties, "conformationally native subunit. etc," it is noted that such property is deemed to describe a mechanism of action which would be inherent in the composition formed by the Cleland et al reference See Examples and claims of Tice et al.

Response to the Arguments

Applicants' amendments and remarks submitted June 27, 2006 have been fully considered, but are not persuasive.

Applicants argue that since the cited references do not expressly teach the employment of gp 160, it would not obvious to use gp 160 in the microsphere disclosed in the prior art. Such arguments are untenable. As to Tice reference, which is a US patent, it is noted that Tice expressly claimed that the active agent be antigen or vaccine. Therefore, one ordinary skill in the art would have reasonably expected that Tice's method would be valid for antigen and vaccine. As to Cleland reference, applicants argue that since gp 160 is distinct from gp 120 structurally, it would not be obvious to use gp 160 in Cleland's microsphere. It is noted that Cleland et al.

merely use gp 120 as an example, but not limit their invention to the particular antigen. See, particularly, the abstract and the claims. Furthermore, it is well settled that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ. 423 (CCPA 1971).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617